

REMARKS

This Amendment is supplemental to the Amendment filed on July 18, 2005 with the RCE. As per the RCE filed on July 18, 2005, the present application is subject to continued examination. Any previous reference to a continuation application should be disregarded. Accordingly, the current amendment to the specification accurately reflects this status.

The Office Action dated February 17, 2005 has been carefully considered. The present Amendment, taken with the Amendment filed on July 18, 2005, are believed sufficient to establish the patentability of the claims and place the present application in condition for allowance. An early allowance is respectfully requested.

Claims 1-58 are pending in the application and subject to examination.

35 U.S.C. § 102

Claims 1-16, 18-30, 33-43, 49, 51 and 53-55 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Application Serial No. 5,879,666 to Lucas et al (Lucas '666) or U.S. Application Serial No. 5,874,067 to Lucas et al. (Lucas '067) (collectively, '666 and '067 are referred to herein as "the Lucas patents"). Specifically, the Examiner asserts that the Lucas patents disclose odor-absorbing compositions comprising up to 5% of uncomplexed cyclodextrin (CD), emulsifiers such as those described instantly, and citric acid, which is safe for human skin. The Examiner further points to examples I-III of Lucas as assertedly disclosing the specific castor oil surfactant recited in instant claim 1. The Examiner maintains that the claim limitations regarding the % and the level of functionally available CD are inherent in the compositions of Lucas because the uncomplexed CD disclosed "is the same amount as claimed," and further maintains that Lucas discloses the same surfactants as

claimed and hence the critical micelle concentration and Clog P values claimed are inherent to the surfactants of Lucas. This rejection is traversed and reconsideration is respectfully requested.

Instant independent claim 1 is directed to a composition suitable for capturing unwanted molecules from a surface. The composition comprises functionally-available cyclodextrin and a cyclodextrin-compatible surfactant selected from the group consisting of castor oil surfactant, polyethoxylated fatty alcohol surfactant, polypropoxylated fatty alcohol surfactant, glycerol mono-fatty acid ester surfactant, polyethylene glycol fatty acid ester surfactant, polypropylene glycol fatty acid ester surfactant, fluorocarbon surfactant, and mixtures thereof; wherein the concentration of functionally-available cyclodextrin, as applied to the surface, is at least about 0.001%.

Instant independent claim 53 is directed to a composition suitable for capturing unwanted molecules from a surface. The composition, as applied to the surface, comprises at least about 0.001% of functionally-available cyclodextrin, a cyclodextrin-compatible surfactant selected from the group consisting of castor oil surfactant, polyethoxylated fatty alcohol surfactant, polypropoxylated fatty alcohol surfactant, glycerol mono-fatty acid ester surfactant, polyethylene glycol fatty acid ester surfactant, polypropylene glycol fatty acid ester surfactant, fluorocarbon surfactant, and mixtures thereof, a buffering agent having at least one pK_a value and/or pK_b value of from about 2 to about 11, and a cyclodextrin-compatible antimicrobial active, wherein the composition has a pH of from about 3 to about 9. In addition, in response to previous arguments submitted by Applicants, the Examiner states that the Lucas compositions may be anticipating even though they contain components which complex with CD because the "comprising" language of the instant claims allows such

additional components (see Feb. 12, 2005 Office Action, page 5, second full paragraph). The Examiner also asserts that the present specification teaches "uncomplexed cyclodextrin as being able to weakly complex with certain molecules, thus allowing for some complexation of cyclodextrin." *id.*

Applicants acknowledge that the "comprising" language of claims 1 and 53 permits the presence of components in addition to the explicitly recited components. However, Applicants point out that this inclusive term still only permits inclusion of components which comport with the functional recitation of the claim, that is, the CD must be "functionally available" at the surface, as required by both independent claims 1 and 53.

Applicants point out that the present specification defines "functionally available CD" as referring to CD "that is either not complexed with other materials, or is complexed with materials that only weakly complex with CD, e.g. weakly complexing materials that have a CD complexation constant of less than about $5,000 \text{ M}^{-1}$ " (page 3, lines 31-33 bridging to page 4, line 1). Hence, by definition, the presence of a strongly complexing material, which is accessible to the cavity of the uncomplexed or weakly complexed CD, defeats functional availability. Applicants submit that it is knowledge common to the art that materials with a weaker CD-complexation constant will ultimately be displaced from the CD cavity by a material with a higher complexation constant in environments where access to the CD cavity is not impeded or otherwise controlled. Applicants fail to find any explicit or implied teaching in either Lucas '666 or Lucas '067 that access to the CD cavity is controlled.

It is important to understand that "functional availability," as presently defined and employed, does not turn solely on the presence of weakly or un-complexed CD, but must take into consideration the presence of other strongly complexing molecules which will eventually

displace the weakly complexing molecule from the CD cavity, forming its own inclusive complex with the CD and rendering it functionally unavailable to capture unwanted molecules from a surface. In other words, weakly complexed CD is functionally available when standing alone, but weakly complexed CD is not functionally available in the presence of strongly complexing molecules since as soon as the bound molecule leaves the CD cavity, the cavity will be competitively occupied by the stronger complexing material. Therefore, a composition comprising molecules available to complex strongly with CD does not meet the functional requirement of the instant independent claims even if it is originally formulated with weakly or un-complexed CD because the composition is not suitable to capture unwanted molecules *from a surface*.

Instant independent claims 1 and 53 explicitly require that the CD be functionally available, not just as added to the composition, but at the surface of the substrate having unwanted molecules. Hence, CD is "functionally available" within the meaning of the present claims, applies not just because it is uncomplexed or weakly complexed CD, but because its cavity is protected from access by strongly complexing molecules. Functionally available CD must exist in the composition at competitive equilibrium with the other components of the composition, such that the CD is functionally available *to bind with unwanted molecules on a surface*. If they bind, instead, with strongly complexing molecules present in the composition itself, prior to contact with a surface, then they are not functionally available within the meaning of the present claims.

Applicants note that the compositions disclosed by the Lucas patents in examples I-III and asserted by the Examiner to be anticipating, all contain an ingredient known as Dow Corning 365 (DC365), which is a 35% dimethicone (methylated siloxanes) solution also

containing several non-ionic surfactants and preservatives. In addition, the Lucas compositions contain other components such as octylphenoxy polyethoxy ethanol and PEG sorbitan monolaurate, which complex with CD. In addition, the compositions disclosed by Lucas teach DC365 formulated into the compositions in amounts 5 to 10 times greater than the CD component, shifting the equilibrium toward formation of complexes between CD and some component of DC365.

Anticipation under 35 U.S.C. § 102(b) requires the disclosure in a single prior art reference of each element of the claims under consideration, *Alco Standard Corp. v. TVA*, 1 U.S.P.Q.2d 1337, 1341 (Fed. Cir. 1986). Moreover, to serve as an anticipating reference, the reference must enable that which it is asserted to anticipate. "A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003). The Lucas patents fail to teach, either explicitly or inherently, compositions comprising functionally available CD suitable for capturing unwanted molecules from a surface, as recited in the present claims and defined according to the instant specification. Moreover, the teachings of the Lucas patents do not enable the present invention, as they do not meet the functional limitation of the instant claims. Hence, the rejection of claims 1-16, 18-30, 33-43, 49, 51 and 53-55 under 35 U.S.C. § 102(b) has been overcome and reconsideration is respectfully requested.

35 U.S.C. § 103

Claims 44, 50, 52 and 56-58 are rejected under 35 U.S.C. § 103 as being unpatentable over Lucas '666 or Lucas '067 (collectively, "the Lucas patents"). Specifically the Examiner notes that neither Lucas patent teaches the use of the compositions in a fabric softener, on a

fabric, or for hard surfaces, and that neither discloses the specific quaternium antimicrobial compounds and the pH of claim 58. The Examiner asserts, however, that both discuss the utility of CD containing compositions for odor absorption on fabrics and general odor absorption properties of CD so that it would have been obvious by one of ordinary skill in the art "to use CD for treating animate as well as inanimate surfaces" because "the efficacy of CD to absorb odor would still be maintained irrespective of the surface being treated..." The Examiner further asserts that any suitable antimicrobial agent, and adjusting the pH of the composition without losing CD activity, would have been obvious because Lucas '666 suggests that a pH of 3.5-8 is suitable. This rejection is traversed and reconsideration is respectfully requested.

Independent claims 1 and 53 are set forth in detail above.

The deficiencies of the Lucas patents with respect to independent claims 1 and 53 are discussed above. Applicants submit that not only do the Lucas patents fail to teach or disclose the compositions recited in claims 1 or 53, neither do they *suggest* the inventive compositions. The Lucas patents fail to teach or disclose compositions comprising, inter alia, functionally-available cyclodextrin, suitable for capturing unwanted molecules from a surface, wherein the concentration of functionally-available cyclodextrin, as applied to the surface, is at least about 0.001. Indeed, as discussed above, the compositions disclosed by the Lucas patents contain a very high percentage of molecules which would shift the equilibrium toward the existence of complexed CD.

In order to render a claimed invention obvious, the prior art must enable one skilled in the art to make and use the claimed invention, *Motorola, Inc. v. Interdigital Tech. Corp.*, 43 U.S.P.Q.2d 1481, 1489 (Fed. Cir. 1997). The Lucas patents fail to teach or suggest

compositions comprising functionally available CD, in combination with the other recited components, wherein the composition is suitable for capturing unwanted molecules from a surface. Applicants acknowledge that the Lucas patent compositions may be formulated with uncomplexed or weakly complexed CD ingredients. However, as formulated they would not comprise functionally available CD suitable for capturing unwanted molecules from a surface, as required by present independent claims 1 and 53, because they also contain components which would competitively occupy the CD cavity. Hence independent claim 1 and claims 44, 52 and 58 dependent therefrom, and independent claim 53, and claims 56-57 dependent therefrom are nonobvious and patentably distinguishable from the Lucas patents.

Present independent claim 45 is directed to a process of manufacturing a composition suitable for capturing unwanted molecules from a surface comprising the steps of: (a) providing cyclodextrin, a cyclodextrin-compatible surfactant, and a cyclodextrin-incompatible material; (b) combining the cyclodextrin-compatible surfactant and the cyclodextrin-incompatible material to form a first mixture, wherein the cyclodextrin-incompatible material is maintained in molecular aggregates in the first mixture; and (c) subsequently combining the cyclodextrin with the first mixture to form the composition suitable for capturing unwanted molecules from a surface, wherein the composition comprises functionally available cyclodextrin.

With respect to independent method claim 45, Applicants note that since the Lucas patents fail to teach or suggest compositions comprising, inter alia, functionally available CD suitable for capturing unwanted molecules from a surface, they clearly do not teach or suggest methods for manufacturing such compositions. In particular, Applicants submit that, as taught in the present specification at page 23, bridging to page 24, the process embodiment

of claim 45 provides a formulation process whereby components that previously were omitted from CD compositions because they would competitively bind with the CD, may be included in CD compositions such that the CD remains functionally available and the composition is suitable for capturing unwanted molecules. Specifically, as disclosed in the specification at page 23, lines 11-13, compositions can be carefully formulated, as recited in instant claim 45, to comprise both CD-incompatible materials and functionally available CD.

The Lucas patents, on the other hand, do not disclose significance to the order of component addition or any other adaptation of their formulations which would prevent access by the CD-incompatible materials, to the cavity of the CD. Significantly, Applicants are not asserting that compositions comprising both CD-compatible and CD-incompatible materials, or processes for making them, are novel, or that the formation of molecular aggregates from such mixtures is novel. However, Applicants submit that their discovery, that mixing certain CD-compatible and CD-incompatible materials together prior to the addition of CD such that the CD-incompatible materials are maintained in molecular aggregates and not accessible to the cavity of the CD, permits the formulation of compositions comprising both CD-incompatible material and functionally available CD and is novel and patentably distinguishable over the known art, including the Lucas patents.

To establish prima facie obviousness of the claimed invention, all the claim limitations must be taught or suggested by the prior art, *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). Furthermore, references relied upon to support a rejection under 35 U.S.C. §103 must provide an enabling disclosure, i.e., they must place the claimed invention in the possession of the public, *In re Payne*, 203 U.S.P.Q. 245 (CCPA 1979). The Lucas patents fail to teach or suggest methods for manufacturing compositions comprising,

inter alia, functionally available CD and suitable for capturing unwanted molecules from a surface. In particular, the Lucas patents fail to teach or suggest methods comprising, inter alia, combining the cyclodextrin-compatible surfactant and the cyclodextrin-incompatible material to form a first mixture, wherein the cyclodextrin-incompatible material is maintained in molecular aggregates in the first mixture and subsequently combining the cyclodextrin with the first mixture to form the composition suitable for capturing unwanted molecules from a surface, wherein the composition comprises functionally available cyclodextrin. Hence, independent claim 45 and claim 50 dependent therefrom is patentably distinguishable from the Lucas patents.

For these reasons, the rejection of claims 1, 44, 45, 50, 52 and 56-58 over the Lucas patents is overcome. Reconsideration is respectfully requested.

Claims 17, 31, 32, and 45-48 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Lucas patents, in view of Hodul et al. ("Tenside, Surfactants & Detergents, 1997) or in view of Hodul and Dharmawarana et al. (Langmuir, 1993). The Examiner notes that neither of the Lucas patents teaches the claimed method of preparation and "aggregate formation of CD and surfactants," but that Hodul studied the functional properties of inclusion complexes of nonionic surfactants and studied properties such as wetting efficiency, foaming, detergent efficiency, etc., and suggests that inclusion complexes of CD with polyethoxylated higher fatty alcohols increases the detergent efficiency to that of polyethoxylated alkyl phenols.

The Examiner asserts that Langmuir teaches a method of determining binding constants for CD-surfactant inclusion complexes. The Examiner characterizes this method as involving measuring the change in surface tension caused by addition of CD to aqueous

solution of surfactants and correlates this to surfactant activity. The Examiner further asserts that Langmuir teaches that surface tension is a function of the amount of CD and that the binding constants relate to micelle formation. The Examiner concludes that it would have therefore been obvious to a person of ordinary skill in the art that CD and surfactant interaction play an important role in the detergency or surfactant efficiency of the compositions of Lucas so that it would have been obvious "to choose the amounts of surfactants (compatible or incompatible with CD) such that the desired composition (homogenous versus aggregates) is obtained without sacrificing the odor-absorbing property of cyclodextrin." This rejection is traversed and reconsideration is respectfully requested.

Claim 45, as set forth in detail above, is directed to a process of manufacturing a composition suitable for capturing unwanted molecules from a surface comprising the steps of: (a) providing cyclodextrin, a cyclodextrin-compatible surfactant, and a cyclodextrin-incompatible material; (b) combining the cyclodextrin-compatible surfactant and the cyclodextrin-incompatible material to form a first mixture, wherein the cyclodextrin-incompatible material is maintained in molecular aggregates in the first mixture; and (c) subsequently combining the cyclodextrin with the first mixture to form the composition suitable for capturing unwanted molecules from a surface, wherein the composition comprises functionally available cyclodextrin.

First, Applicants respectfully submit that the Examiner mischaracterizes the embodiment as recited in present claim 45. In particular, the Examiner's assertion that Hodul's disclosure of relative detergent efficiency between various CD-surfactant inclusion complex does not appear to have relevance to the practice or objective of the present claim. It does not cure the deficiencies of the Lucas patents, detailed above, as it fails to teach or

suggest formulation manipulations which impede or prevent access by CD-incompatible materials to the cavity of CD in compositions comprising both CD and CD-incompatible materials. On the contrary, the teachings of Hodul focus on the formation of complexes between CD and surfactants, a result sought to be minimized by the present invention.

In addition, with respect to Langmuir, the Examiner asserts that the Langmuir teachings relate to calculating binding constants for CD-surfactant complexes and micelle formation and concentrations. Applicants respectfully point out that the presently recited method involves forming a first mixture of CD-incompatible material and CD-compatible surfactant. CD itself is not a component of the first mixture and is not a component of the recited aggregate. The CD required by method claim 45 is not added until after the formation of the aggregates. The objective of aggregate formation, according to the present teachings, is to tie up the CD-incompatible material so that it cannot access the cavity of the subsequently added CD (specification page 42, lines 26-30, and, throughout the specification, for example, at page 13, line 16-17). The aggregates and micelles of the present invention are formed between the CD-incompatible material and the CD-compatible surfactant, and not between the CD and a surfactant as disclosed by both Hodul and Langmuir.

Since the teachings of Hodul and Langmuir are inapposite to the objective or practice of independent claim 45 and claims dependent therefrom, they do not overcome the deficiencies of the primary references, the Lucas patents. Hence claim 45 and claims 46-48 are patentably distinguishable from the combination of the Lucas patents in view of Hodul or Hodul and Langmuir.

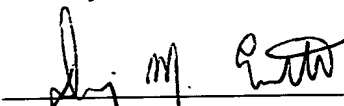
Likewise, instant claim 17 is directed to a composition comprising, inter alia, "molecular aggregates comprising said cyclodextrin-compatible surfactant and said

cyclodextrin-incompatible surfactant," instant claim 31 is directed to the composition of claim 17 wherein "said molecular aggregates are micelles or vesicles comprising said cyclodextrin-compatible surfactant and said cyclodextrin-incompatible surfactant," and instant claim 32 is directed to a composition according to Claim 17 wherein all surfactants in the composition form part of said molecular aggregates. It is readily ascertainable from these recitations that the molecular aggregates, including micelles or vesicles, are formed between the CD-incompatible material and the CD-compatible material, and CD is not involved. The teachings of Hodul are related to complexes between CD and surfactants and the teachings of Langmuir relate to aggregate formation and other interactions between CD and surfactants. Hence, these references are unrelated to the instantly rejected claims and do not overcome the deficiencies of the primary reference, the Lucas patents.

For these reasons the rejection of claims 17, 31, 32, 45 and 46-48 under 35 U.S.C. § 103(a) under the Lucas patents in view of Hodul or in view of Hodul and Langmuir is overcome. Reconsideration is respectfully requested.

It is believed that the foregoing constitutes a complete and particularized response to the rejections of claims 1-58 under 35 U.S.C. §§ 102 and 103. Reconsideration and an early allowance is respectfully requested.

Respectfully submitted,

By: 
Denise M. Everett
Registration No. 47,552
Attorney for Applicants
Dinsmore & Shohl LLP
1900 Chemed Center
255 East Fifth Street
Cincinnati, OH 45202
(513) 977-8787